REMARKS

In response to the Office Action dated August 9, 2006, Applicants respectfully request that the above amendments be entered and the following remarks be considered. Claims 1-14 and 17-24 are currently pending in the application. Claims 4, 5 and 19 have been withdrawn. Claims 6 and 20 have been cancelled. Claims 1-5, 7-14, 17-18 and 21-24 are believed to be in condition for allowance and such favorable action is respectfully requested.

Objections

Table 1 has been objected to as it is stated that Table 1 does not correspond to information presented in Table 2. Applicants respectfully traverse this objection. Table 1 shows 98 IBD patients in row 1. The IBD patients had CD and UC. As such, the 98 IBD patients were further broken down into 47 CD patients and 51 UC patients in rows 2 and 3 of Table 1. Row 4 depicts seven (7) patients with IBS and row 5 depicts eleven (11) healthy patients. As such, a total of only 116 patients (47 CD, 51 UC, 7 IBS and 11 healthy) had his or her fecal sample tested for ANCA. (Specification Table 1 and Paragraph 18). Of the 116 total patients tested, only twenty six (26) tested positive for ANCA. The other 90 patients tested negative for ANCA. Of the twenty six (26) patients who tested positive for fecal ANCA, twenty one (21) were patients who had ulcerative colitis, four (4) had Crohn's disease and one (1) was a healthy person. (See Specification, Paragraph 18.) Table 2 displays the mean, standard deviation and P values for optical densities for all 21 UC patients who tested positive for ANCA, all 4 CD patient's who tested positive for ANCA, for all 7 IBS patients tested, and for all 11 healthy patients tested (including the one who tested positive for ANCA). As such, there is not a disappearance of 171 patients from Table 1 to Table 2. Table 1 depicts the total number of

patients tested and Table 2 depicts the number of UC and CD patients who tested positive for fecal ANCA and the 7 IBS and 11 healthy patients tested.

Table 1 has been objected to as it is stated that Table 1 does not correspond to information presented in Table 3. Again, Tables 1 and Table 3 show 98 IBD patients in row 1. The IBD patients had CD and UC. As such, the 98 IBD patients were further broken down into 47 CD patients and 51 UC patients in rows 2 and 3 of Table 1 and 3. Row 4 depicts seven (7) patients with IBS and row 5 depicts eleven (11) healthy patients. As such, a total of only 116 patients had his or her fecal sample tested for ANCA. (Specification Table 1 and Paragraph 18). These numbers are consistent in both Table 1 and Table 3. As such, there is not a disappearance of 98 patients from Table 1 to Table 3.

It is stated that the information presented in Table 2 does not correspond with Table 3. Applicants submit that the information does correspond as a total of 116 patients total: 47 with Crohn's disease, 51 patients with ulcerative colitis, (the 47 UC and 51 CD patients make up the 98 IBD patients) seven patients with IBD and 11 healthy persons are shown in Table 1 and 3. Table 2 depicts the UC and CD patients who tested positive of for fecal ANCA and all 7 IBS and 11 healthy patients tested. Again, only 26 out of 116 patients test positive for fecal ANCA. Of the twenty six (26) patients who tested positive for fecal ANCA, twenty one were patients who had ulcerative colitis, four (4) had Crohn's disease and one (1) was a healthy person. (See Specification, Paragraph 18.) Table 2 displays the mean, standard deviation and P values for optical densities for all 21 UC patients who tested positive for ANCA, all 4 CD patient's who tested positive for ANCA, for all 7 IBS patients tested, and for all 11 healthy patients tested (including the one who tested positive for ANCA).

As the Tables correctly list the data, Applicants request withdrawal of the objection to Tables 1-3.

35 U.S.C. § 112, Second Paragraph, Rejections

Claims 2, 3, 8-13, 17, 18, and 20-24 have been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In particular, the Office Action states that in claims 2, 12 and 17, the passive voice recitation "is concluded" is indefinite. Applicants submit that claims 2, 12 and 17 have been amended to conduct an active step. As such, Applicants request withdrawal of the § 112 rejection of claims 2, 12 and 17.

Claims 2-3 have been rejected as the recited steps to not appear to be relevant to a method of "testing a fecal sample" as recited in the preamble of claim 1. Applicants have amended the preamble of claim 1 and now submit that the language is definite and request withdrawal of the §112 rejection.

Claims 3 and 18 have been rejected for using the passive voice recitation "is used." Claims 3 and 18 have been amended to utilize an active voice. As such, Applicants submit that the language is definite and request withdrawal of the §112 rejection of these claims.

Claims 6 and 20 have been rejected for use of the recitation "total anti-neutrophil cytoplasmic antibodies." Applicants have canceled claims 6 and 20.

Claim 11 has been rejected claiming the preamble does not correspond to the method outcome. Applicants have amended the preamble accordingly and request withdrawal of this rejection.

Claim 14 has been rejected for the use of "the diagnostic assay as recited in claim 1." Claim 14 has been amended to depend from claim 11. As such, Applicants request withdrawal of the rejection.

Claim rejections 35 USC § 101

Claims 1-3, 6-14, 17, 18 and 20-24 have been rejected under 35 USC § 101 stating the claimed invention lacks credible utility. Applicants respectfully traverse this rejection and assert that the claimed invention has patentable utility.

According to MPEP 2107.01 "[p]ractical utility is a shorthand way of attributing 'real-world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public. *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980)." Applicant submits that the method for testing a fecal sample for an elevated level of anti-neutrophil cytoplasmic antibodies, wherein an elevated level of anti-neutrophil cytoplasmic antibodies is an indicator of ulcerative colitis provides a benefit to the public and is consistent with the logic underlying Applicants' assertion.

According to the Office Action is stated that Applicant's assertion of specific utility is not credible because, according to Table 4 of Applicant's specification, only 41% of patients presenting with UC possessed ANCA (i.e., ANCA is a useful indicator of ulcerative colitis.) However, Applicants submit that they are not claiming that all patients' with ulcerative colitis test possess ANCA and this statement is utilizing the reverse logic.

Rather, Applicants are claiming if a patient's sample contains elevated level of anti-neutrophil cytoplasmic antibodies, the elevated level of anti-neutrophil cytoplasmic antibodies is an indicator of ulcerative colitis. Thus, while not all patients with UC have an elevated level of ANCA, those who do have an elevated level can be diagnosed with UC, rather

than CD or IBS. Thus, while the test only detects ANCA in 41% of UC patients (Sensitivity), in the 41% of the patients who have ANCA, the test is 92% accurate in diagnosing UC (Specificity). The specificity refers to how well a positive result of ANCA correlates to a diagnosis of UC.

Only a small fraction of those who test positive for ANCA had another condition or were healthy (8%). As such, an elevated level of ANCA can be used to provide a diagnosis of UC in those patients who have an elevated level. As such, when utilized by clinician the method and assay of the present invention, clearly aids a clinician in diagnosing UC rather than diagnosing IBS or CD as very few patients with CD and IBS test positive for ANCA.

Furthermore, according to MPEP 2107.01, "[p]ractical considerations require the Office to rely on the inventor's understanding of his or her invention in determining whether and in what regard an invention is believed to be 'useful.' Because of this, Office personnel should focus on and be receptive to assertions made by the applicant that an invention is 'useful' for a particular reason." Applicants respectfully submit that the invention as claimed is "useful" as described above and request withdrawal of the §101 rejection of claims 1-3, 6-14, 17, 18 and 20-24.

Claim rejections 35 USC §112, first paragraph

Claims 1-3, 6-14, 17-18 and 20-24 have been rejected under 35 USC §112, first paragraph stating that the claimed invention is not set forth by a credibly-asserted utility. Applicants submit that the claimed invention has a specific credibly-asserted utility as stated with reference to the §101 rejection. As such, Applicants request withdrawal of the §112 rejection of claims 1-3, 6-14, 17, 18 and 20-24.

CONCLUSION

Each of claims 1-3 7-14 and 17, 18 and 21-24 is believed to be in condition for allowance, and a timely notice of allowance solicited. Should it be determined that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

It is believed that no additional fee is due in conjunction with the present Amendment. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required, or credit any overpayment, to Deposit Account No. 19-2112.

Respectfully submitted,

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